

**REMARKS**

Claims 1-9 and 21-37 remain pending.

**35 U.S.C. § 112 Rejections**

Claims 1-20 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants traverse these rejections.

The Office Action alleges that the phrase “free of a bulking agent” is indefinite. Applicants respectfully disagree and traverse this rejection. As made clear by the Federal Circuit, the claims must be read in light of the specification as it is the best single guide to the meaning of a disputed claim. *Phillips v AWH Corp.*, 415 Fed.3d 1303 Fed. Cir.2005, cert denied 2006 US Lexus 1154 (Feb. 21, 2006) Applicants’ specification states on page 6 – page 7:

As is known to one of skill in the art, a carrier and /or bulking agent is an inert substance in which or on to which the active drug ingredient(s) and excipient(s) if present are dispersed. When the formulations of the present invention utilize HFA 227 as the propellant, it has been surprisingly found that a carrier is not necessary. Accordingly there is disclosed a metered dose inhaler containing an aerosol suspension formulation for inhalation, said aerosol suspension formulation for inhalation comprising: an effective amount of mometasone furoate and HFA 227, wherein the formulation is substantially free of a carrier. The processes for producing the formulations of the present invention preferably utilize HFA 227 or HFA 134a, or a combination thereof, in combination with mometasone furoate and dry powder surfactant.

In light of the specification, it is unclear to the Applicants why the Office Action would conclude that the propellant, specifically HFA 227, is encompassed by the term “bulking agent”. The specification clearly distinguishes the terms “propellant” and “bulking agent”. The specification states at page 6, lines 12-13, “the propellant serves as a vehicle for both the active ingredients and excipients.” The specification separately defines a bulking agent at page 6, line 23 to page 7, line 1 as “an inert substance in which or on to which the active drug ingredient(s) and excipient(s) if present are dispersed.” The specification then goes on to distinguish HFA 227 from a bulking agent. Applicants submit that bulking agent is clearly defined in the specification.

Further, the PTO guidelines do not support the present rejection. M.P.E.P. §2173.02 clearly states that “the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available,” and that the definiteness of claim language must be analyzed in light of “[t]he claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” Applicants submit that a worker skilled in the art would readily appreciate that HFA 227 is not a bulking agent as that term is used in the present application. Accordingly, a skilled worker would not regard the language “free of a bulking agent” as indefinite. Applicants therefore respectfully request reconsideration and withdrawal of this §112, second paragraph rejection.

Claims 8, 9, and 36-37 are rejected under § 112 as being incomplete for omitting essential elements. Applicants traverse these rejections. The Action seems to suggest that the origin of the claimed particulate size must be identified. Applicants submit that the recited limitations in these claims are observed characteristics of the claimed composition. The observed characteristics are a result of the claimed subject matter. Applicants submit that there are no missing essential elements to the claims as presented. Applicants respectfully request reconsideration.

### **35 U.S.C. § 102 Rejections**

Claims 1, 6-9, 21, 26, 28-30 and 36-37 are rejected under § 102 as being anticipated by Fassberg. Applicant traverse these rejections. Applicants note that the Examiner does not present a case why the independent claims 1, 21 and 30 are anticipated. The Action is deficient in providing any specific discussion or basis for rejecting claims 1, 6-7, 21, 26, 28-30. Applicants submit that the independent claims are not anticipated and that all of the rejected claims are in condition for allowance. Applicants note that the amended and newly added claims were in response to Office’s suggestions during a seemingly favorable interview held on October 5, 2006. Applicants respectfully request reconsideration.

Applicants note that the Examiner provides a detailed discussion about making an MDI. Applicants are confused about why this discussion was added to the Action

considering the fact that none of the pending claims is directed to method of manufacturing. However, the canceled claims 10-19 were directed to a process of producing an aerosol suspension.

**35 U.S.C. § 103 Rejections**

Claims 1-9 and 21-37 stand rejected under 35 U.S.C. § 103(a) over the same references that were of record in the previous Actions. Applicants traverse all of these rejections. All of the current §103 rejections reference the rejections stated in the prior Office Actions. Applicants note that the previous Office Actions did not give weight for examination purposes to the requirement that the formulation be free of a carrier. Applicants submit that none of the current claims have this limitation but do have other limitations that should be separately examined. As such, Applicants submit that the present rejections and the references to prior Actions are deficient and not acceptable. Applicants respectfully request fresh examination of the current pending claims.

The Action states that 'In favor of compact prosecution and in anticipation of Applicants' future claim amendments, claims 1, 6-9, 21, 26, 28-30 and 36-37 have been included in the instant rejection.' The Action goes on to summarize that claims 1-9 and 21-37 covered under this rejection. Applicants are confused and curious as to what is meant by these statements and would like to know what our future claim amendments will be. Additionally, Applicants are unsure how the Action makes the leap of rejecting some of the claims to all of the claims without specifically identifying the rejections.

Based on the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance and request favorable consideration.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Barry Jacobsen", written over a horizontal line.

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